BIOMARKERS OF TOBACCO EXPOSURE: A PUBLIC WORKSHOP

CENTER FOR TOBACCO PRODUCTS (CTP)
FDA White Oak Conference Center
Building 31, Room 1503, 10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
August 3-4, 2015
Agenda

Times and speaker order are tentative and subject to change without notice

Monday, August 3, 2015

8:30 am

Welcome and Introduction of Office Director
Carolyn Dresler, MD, MPA
Associate Director for Medical and Health Sciences, Office of Science
FDA Center for Tobacco Products

Opening Remarks
RADM David L. Ashley, PhD
Director, Office of Science
FDA Center for Tobacco Products

Biomarkers: An Overview
Cindy M. Chang, PhD, MPH
Epidemiologist, Office of Science
FDA Center for Tobacco Products

9:00 am

Session 1: Strategies for Identifying Potential Biomarkers for CTP Regulatory Use

Biomarker Basics: Validation, Qualification, Translation
William B. Mattes, PhD, DABT
FDA National Center for Toxicological Research

Biomarker Utility and Acceptance in Drug Development and Clinical Trials: An FDA Regulatory Perspective
Christopher Leptak, MD, PhD
FDA Center for Drug Evaluation and Research

Biomarkers in Risk Assessment: Use, Challenges, and Lessons Learned
Cecilia Tan, MS, MBA, PhD
EPA National Exposure Research Laboratory

10:30 am	**Break**
10:45 am	**Biomonitoring at the National Institute for Occupational Safety and Health** CAPT D. Gayle DeBord, PhD CDC National Institute for Occupational Safety and Health
	Characterization of Biomarkers to Assess the Utility of Potential Reduced Exposure Tobacco Products: Status Update Dorothy Hatsukami, PhD University of Minnesota
	Integrating Biomarkers into Tobacco Regulatory Science Systems Raymond S. Niaura, PhD Schroeder Institute for Tobacco Research and Policy Studies
12:00 pm	**Lunch**
1:00 pm	**Panel Discussion on Strategies for Identifying Potential Biomarkers for CTP Regulatory Use** William B. Mattes, Christopher Leptak, Cecelia Tan, CAPT D. Gayle DeBord, Dorothy Hatsukami, Raymond S. Niaura, Stephen S. Hecht
1:30 pm	**Session 2: Biomarkers of Exposure and Relationship with Disease Risk**
	A Case Study on the Use of Biomonitoring at EPA: A Cumulative Assessment on Phthalates Matthew Lorber, MS EPA Office of Research and Development
	Biomarkers of Exposure to Tobacco Smoke and Risk of Cancer – The Shanghai Cohort Study Jian-Min Yuan, MD, PhD University of Pittsburgh
	Coherence of Human Findings with Animal Tumor Studies Irina Stepanov, PhD University of Minnesota
3:00 pm	**Break**
3:15 pm	**Two Different Approaches for the Use of Biomarkers of Exposure in the Risk Assessment of Tobacco Products** Kristin M. Marano, MS, MPH, CPH RAI Services Company
	Metals as Non-specific Tobacco Biomarkers of Cardiovascular Disease Miranda Jones, MHS, PhD Johns Hopkins University Bloomberg School of Public Health

Relationship Between Biomarkers of Tobacco Exposure and Disease Risk
Mohamadi Sarkar, M.Pharm, PhD, FCCP
Altria Client Services

Leveraging Population Studies for Tobacco Biomarker Research
Neal Freedman, PhD, MPH
National Institutes of Health/National Cancer Institute

4:40 pm **Panel Discussion on Biomarkers of Exposure and Relationship with Disease Risk**
Matthew Lorber, Jian-Min Yuan, Irina Stepanov, Kristin M. Marano, Miranda Jones, Mohamadi Sarkar, Neal Freedman, Cecilia Tan

5:00 pm **End of Workshop Day 1**

Tuesday, August 4, 2015

8:30 am **Welcome**
Carolyn Dresler, MD, MPA
Associate Director for Medical and Health Sciences
FDA Center for Tobacco Products

8:35 am **Public Comment Session**

9:35 am **Session 3: Identifying Biomarkers of Tobacco Exposure for CTP Regulatory Use**

Biomarkers of Exposure to Tobacco Carcinogens and Toxicants
Stephen S. Hecht, PhD
University of Minnesota

Biomarkers of Tobacco Exposure for CTP Regulatory Use: Utility and Challenges
Kimberly Frost-Pineda, PhD, MPH
Altria Client Services

Lessons from Clinical Studies Using Biomarkers of Exposure to Assess Toxicant Exposure
Christopher Proctor, BSc (Hon), PhD
British American Tobacco Research and Development

10:55 am **Break**

11:10 am **Nicotine and Tobacco Alkaloids: Biomarkers of Tobacco Use and Exposure**
Gideon St.Helen, PhD
University of California, San Francisco

Importance of Analytical Methods for Biomarker Measurement
Benjamin Blount, PhD
CDC National Center for Environmental Health

Biomarkers of Tobacco Exposure in Exhaled Breath
Marielle C. Brinkman, Senior Research Scientist
Battelle Public Health Center for Tobacco Research

12:40 pm **Lunch**

1:40 pm **Panel Discussion on Identifying Biomarkers of Tobacco Exposure for CTP Regulatory Use**
Stephen S. Hecht, Kimberly Frost-Pineda, Christopher Proctor, Gideon St.Helen, Benjamin Blount, Marielle C. Brinkman

2:00 pm **Session 4: Biomarkers of Exposure in Smokeless Tobacco and Electronic Nicotine Delivery Systems (ENDS)**

Biomarkers of Exposure for Smokeless Tobacco Products
Dorothy Hatsukami, PhD
University of Minnesota

A Multi-Center, Cross-Sectional Study Of U.S. Tobacco Users, Including Both Exclusive And Dual Use Of Cigarettes, Moist Snuff And A U.S. Snus Brand: Biomarkers Of Exposure
Michael F. Borgerding, PhD
RAI Services Company

New Biomarkers of Tobacco Exposure
Peyton Jacob, III, PhD
University of California, San Francisco

3:20 pm **Break**

3:35 pm **Biomarkers of Exposure to Nicotine and Toxicants Among Exclusive Users of Electronic Cigarettes and Dual Users of Electronic and Tobacco Cigarettes**
Maciej Goniewicz, PharmD, PhD
Roswell Park Cancer Institute

Toxicants in Biofluids Originated from Stable Isotopes of Propylene Glycol in eCigarettes
Raymond Farmen, PhD
Celerion

4:25 pm **Panel Discussion on Biomarkers of Exposure in Smokeless Tobacco and Electronic Nicotine Delivery Systems (ENDS)**
Dorothy Hatsukami, Michael F. Borgerding, Peyton Jacob, III, Maciej Goniewicz, Raymond Farmen, Stephen S. Hecht

4:55 pm **End of Workshop Day 2**

The use of tobacco products, including e-cigarettes, is prohibited in all FDA facilities including buildings, grounds, and parking structures.